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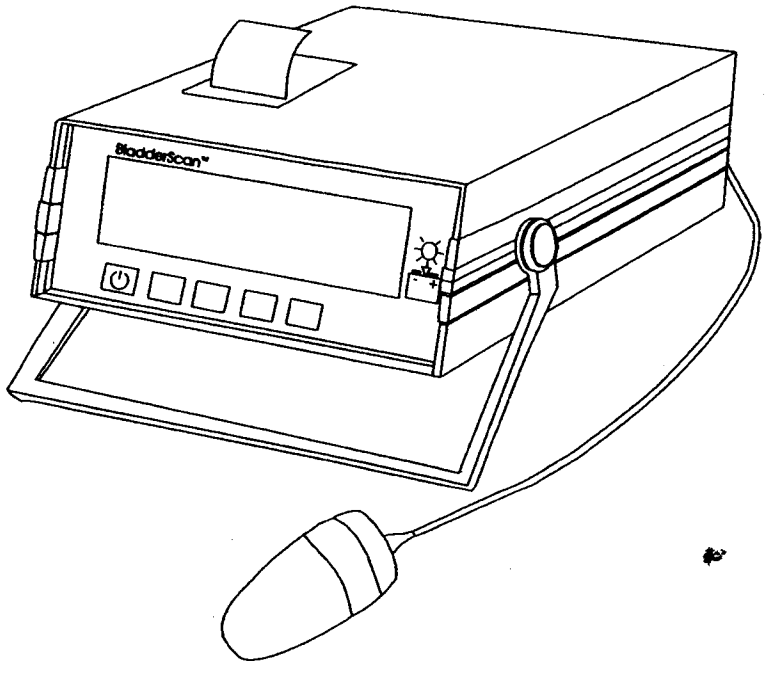
BladderScan™ BVI 2500

Bladder Volume Instrument

Operator's Manual



Diagnostic Ultrasound CORPORATION

Part No. 900-0051-06-60
11/95

BladderScan™ BVI 2500

Bladder Volume Instrument

Operator's Manual

Diagnostic Ultrasound CORPORATION

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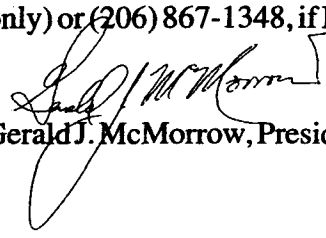
President's Statement

The team at Diagnostic Ultrasound is committed to modernizing health care delivery by "Putting Patients First." Our products support you, the health care providers, by providing the highest level of accuracy, utility and excellence. Please contact me directly at 1-800-331-2313 (USA only) or (206) 867-1348, if I can improve our service to you.



Gerald J. McMorrow, President

Legal Statement

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This instrument is protected by U.S. patent number 4926871. Other international patents pending.

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Important Information

Product Description

The **BladderScan™** BVI 2500 bladder volume instrument is a B-mode ultrasonic device, portable and battery operated, intended for the non-invasive measurement of urinary bladder volume. Utilizing a mechanical sector scanning transducer to provide cross sectional images of the bladder from twelve scanplanes, the machine automatically calculates the estimated bladder volume in milliliters and displays it on a screen.

Notice To All Operators

The BVI 2500 should be used only by individuals who have been trained and authorized by their physician or the institution providing care for the patient. All operators should read this operator's manual prior to using the BVI 2500. Do not attempt to operate the BVI 2500 until all instructions and procedures in this manual have been read and thoroughly understood. Failure to comply with instructions may compromise the performance of the instrument.

Biological Safety

To date, exposure to pulsed diagnostic ultrasound has not been shown to produce adverse effects. Ultrasound, however, should be used only by medical professionals when clinically indicated, using the lowest exposure times possible commensurate with clinical utility.

The ultrasonic output power of the BVI 2500 is not user-adjustable and is limited to the minimum level necessary for effective performance. Data on acoustic output levels can be found in the "Technical Description" section of this manual.

Statement of Prescription

Caution: United States Federal law restricts this device to use by or on the order of a physician.

Statement of Intended Use

The BVI 2500 projects ultrasound energy through the lower abdomen of the nonpregnant patient to obtain an image of the bladder that is used to determine bladder volume non-invasively.

Warning: Not intended for fetal use.

Warning: Not intended to be used on pregnant patients.

Warning: There is a possible explosion hazard if the BVI 2500 is used in the presence of flammable anesthetics.

Cautions

The BVI 2500 should not be used on a patient with open skin or wounds in the suprapubic region.

The patient should not have a catheter in his bladder. This could affect the accuracy of the instrument.

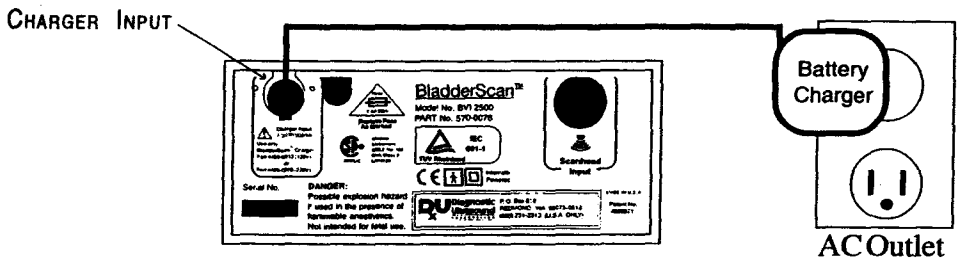
Use care with suprapubic/pelvic surgery patients. Scar tissue, incisions, sutures and staples affect ultrasound transmission and reflection.

Installing the BVI 2500

Charging Battery

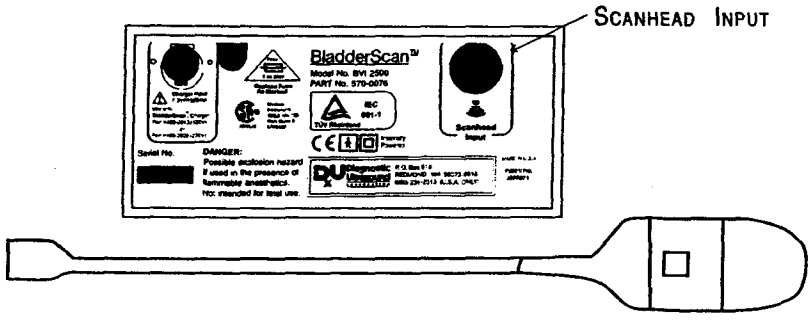
For patient safety, the BVI 2500 always operates from an internal battery and has a safety interlock to prevent normal operation when the battery charger is connected. The battery can be recharged whenever the instrument is not used for patient care. Because the battery may have become discharged in storage and shipment, it may need to be recharged before being used for the first time.

- ☐ To recharge the battery, plug the battery charger into an AC power outlet and the end of the charger cable into the Charger Input socket on the rear panel of the BVI 2500. The charging light on the right side of the front panel will light whenever the battery charger is connected to AC power and to the BVI 2500. The battery requires about 12 hours to charge fully. The light does not go out when the battery is fully charged. The battery charger will not overcharge the battery, so the charger can be left connected at any time the instrument is not in use.



Connecting Scanhead

- ☐ Connect the scanhead cable plug to the Scanhead Input socket on the rear panel of the instrument by aligning the tabs on the plug with the mating slots on the socket. Press straight in until there is a 'click.' To remove the plug, grasp the black plastic ring on the plug and pull straight out. Do not twist.



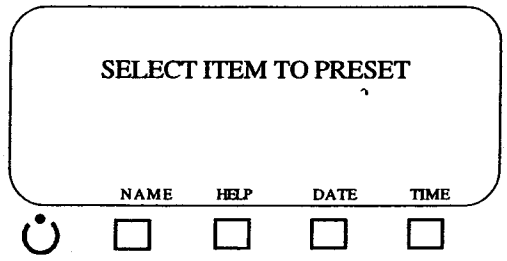
Customizing the BVI 2500

When you first receive the BVI 2500, you should customize it with a name and the current date and time. This name and the correct date/time will then be on all printed results. To customize the BVI 2500, follow these steps:

Setting Name

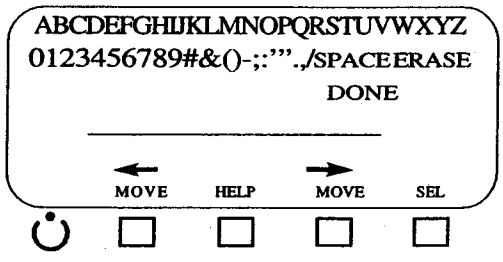
- ☐ Disconnect battery charger by unplugging the charger from the wall outlet and unplugging its power cord from the back of the BVI 2500. The scanhead must be plugged in for the instrument to work.
- ☐ Turn the BVI 2500 on by pressing the button marked: ⏻
- ☐ As soon as the instrument comes on, press the ALT button. The Alternate screen will be displayed.
- ☐ Press the CLOCK/NAME button. The Preset screen will appear.

You can use any combination of up to 27 characters for the user name. For example, you can enter the name of the hospital, clinic or physician where the BVI 2500 will be installed. Note that you can use SPACE to separate words.



- ☐ Press the NAME button. The Name Preset screen will be displayed with alphabetic, numeric and punctuation characters along with space and erase. One of the characters will have an underline cursor under it.

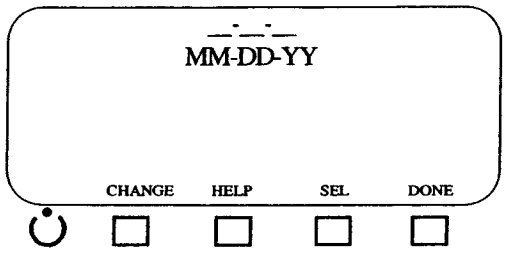
When the MOVE button is held down, the cursor moves one character a second. When the cursor reaches the end of the list of characters, it wraps around to the first character again. When all 27 characters have been selected, the cursor can only be placed under ERASE or DONE.



- ☐ Use the left/right MOVE buttons to put the cursor under the first character of the name that you want to enter.
- ☐ Press the SEL button to select the character. It will appear in the center of the screen.
- ☐ Continue to use MOVE and SEL to enter all the characters in the name. You can also use ERASE to erase the most recently entered character.
- ☐ When you finish entering the name, place the cursor under DONE and press the SEL button. The Alternate screen will be displayed.

Setting Date

☐ From the Alternate screen, press the CLOCK/NAME button and then the DATE button. The Date Preset screen will display the current value for the date in the U.S. format (two numbers for the month, day and year). A cursor will underline the month.



☐ Press the CHANGE button until the correct month is displayed. Only values from 01 to 12 are allowed and 12 is followed by 01.

☐ Press the SEL button. The month is set and the cursor will now underline the day of the month.

☐ Press the CHANGE button until the correct day is displayed. Only values from 01 to 31 are allowed.

☐ Press the SEL button. The day is set and the cursor underlines the year.

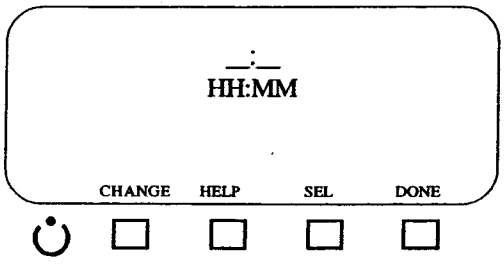
☐ Press the CHANGE button until the correct year is displayed. Only values from 95 to 19 (for 1995 to 2019) are allowed.

☐ Press DONE button. The Alternate screen is displayed.

Once set, the BVI 2500 clock knows the number of days in each month including February during leap years. It has its own lithium battery and maintains the correct date and time for at least ten years, even if the BVI 2500 is unplugged and its main battery discharged.

Setting Time

☐ From the Alternate screen, press the CLOCK/NAME button and then the TIME button. The Time Preset screen will be displayed with the current time. A cursor will underline the hours.



☐ Press the CHANGE button until the correct hour is displayed.

☐ Press the SEL button. The cursor will underline the minutes.

☐ Press the CHANGE button until the correct minute is displayed.

☐ Press the DONE button. The time is set and the Alternate screen is displayed. *You have now customized your BVI 2500.*

Enter the time in the 24-hour format. After Noon add 12 hours to the time to get 24-hour time. For minutes, numbers between 00 and 59 are allowed.

Operating the BVI 2500

First Time Users: *A new operator may want use the BVI 2500 on a patient with a moderately full bladder, rather than initially attempting to locate a nearly empty bladder. In addition, an in-service video tape has been sent with your BVI 2500. Viewing the tape will supplement the information in this manual with an actual demonstration.*

Turning On

Note: To protect the safety of patients, the BVI 2500 will not operate with the battery charger connected.

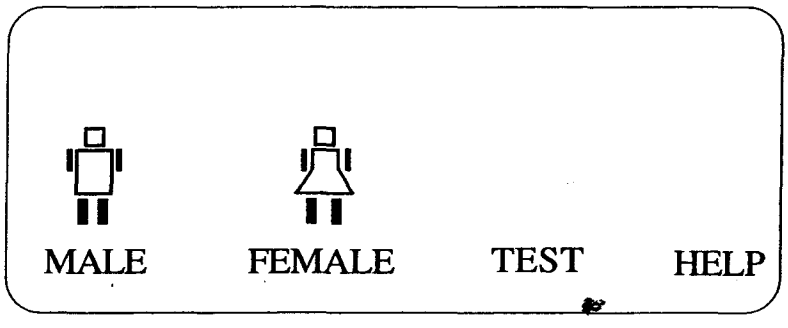
- ☐ Disconnect battery charger by unplugging the charger from the wall outlet and unplugging its power cord from the back of the BVI 2500. The scanhead must be connected for the instrument to work.
- ☐ Turn the BVI 2500 on by pressing the button marked: ⏻

When it powers up, the BVI 2500 will test itself and then display the message: "BVI 2500 (NOT INTENDED FOR FETAL USE)". The screen will also display the customized name, date and time and label three buttons as SCAN, HELP and ALT. This screen will be displayed for five seconds, allowing the user time to select the ALT or HELP buttons. If the SCAN button is pressed, or if no button is pressed within five seconds, the Gender screen will be displayed.

Selecting Gender

Exam Saved Screen: If data from the last exam was never printed, that data will be saved when the instrument is turned off. The next time the BVI 2500 is turned on, the user will be given an opportunity to print the data from an Exam Saved screen which appears after the Gender screen.

The BVI 2500 will first prompt you to enter the gender of the patient being scanned. If the patient is female, this allows the instrument to exclude the uterus, if present, which may resemble the bladder ultrasonically. Use the "MALE" selection if the patient is a female who is known to have undergone a hysterectomy. Select "TEST" when scanning a DxU training phantom.



Preparing the Scanhead

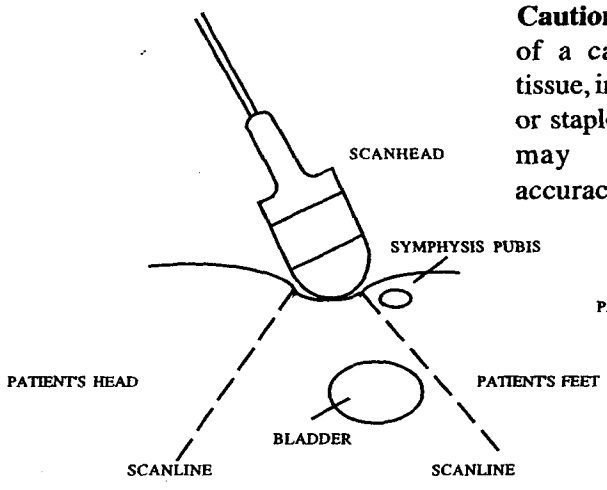
Warning: The BVI 2500 is not intended for fetal use or use on pregnant patients.

- ☐ Clean the rounded end of the scanhead by wiping gently with a cleaning pad dampened with isopropyl alcohol or a hospital disinfectant solution.
- ☐ Apply a generous amount of ultrasound transmission gel on the rounded dome of the scanhead. Smooth the gel out and remove any air bubbles which may block ultrasound transmission.

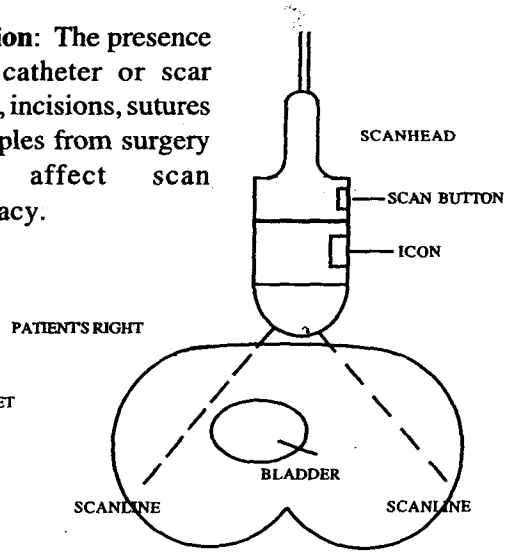
Scanning the Bladder

- ☐ Find the symphysis pubis and place the scanhead about 3 cm (1 inch) superior to the symphysis pubis and pointing toward the expected bladder location. Locate the icon on the probe and make sure the head of the icon is pointed toward the head of the patient.
- ☐ Press the scanhead button marked . Hold the scanhead steady until you hear the beep when scanning has been completed. The Aiming screen will be displayed.

Caution: The presence of a catheter or scar tissue, incisions, sutures or staples from surgery may affect scan accuracy.



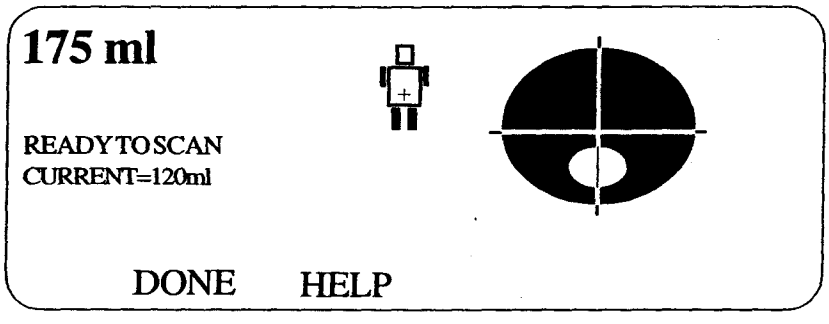
VIEW FROM PATIENT'S RIGHT SIDE



VIEW FROM PATIENT'S FEET

Adjusting Aim

The Aiming screen displays the largest volume measured in the upper left hand corner, the instrument status (ready to scan, scanning, computing), the current volume measurement, and the aiming target.



Note: Accuracy is improved when the patient is reclining quietly in a supine position.

- ☐ If the crosshairs are not centered on the bladder, adjust the probe and rescan until they are centered. The Aiming screen displays the bladder cross section as viewed when looking down into the patient's abdomen.
- ☐ When you are satisfied that the aim is correct, press the DONE button. The Scan Results screen will be displayed.

Greater Than Results

Note: In certain cases, the BVI 2500 will display the volume as ">### ml", where the "###" is the estimated bladder volume. The > (greater than symbol) means that the cone-shaped region scanned by the instrument did not contain the entire bladder, so the true bladder volume may be larger than the displayed volume. The following examples illustrate the possibilities.

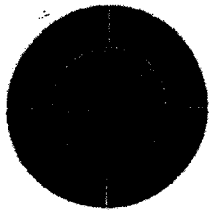


FIGURE 1

Figure 1 shows an aiming screen in which the bladder is completely contained within the scan cone. In this case, the measurement is accurate and the volume is displayed without the > symbol.

FIGURE 2

Figure 2 shows an aiming screen in which the bladder overlaps one side of the scan cone. The instrument recognizes this condition and displays the > symbol. Greater accuracy will be achieved if the examination is repeated with the scanhead repositioned and reaimed.

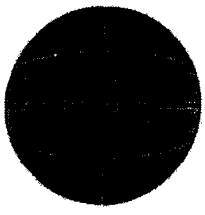
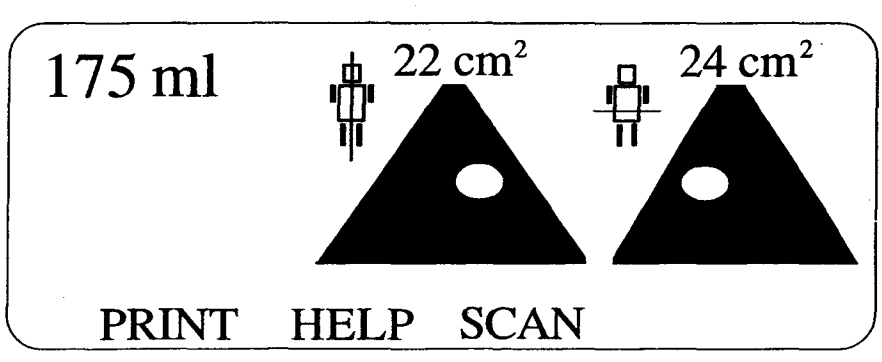


FIGURE 3

Figure 3 shows an aiming screen in which the bladder overlaps two opposite sides of the scan cone. Again the instrument recognizes this condition and displays the > symbol. Since the bladder is too large to be completely contained within the scan cone, repositioning and reaiming the scanhead will do little to improve accuracy. However, this situation arises almost exclusively with very large bladder volumes, so the measurement may be clinically useful even though less than the true bladder volume.

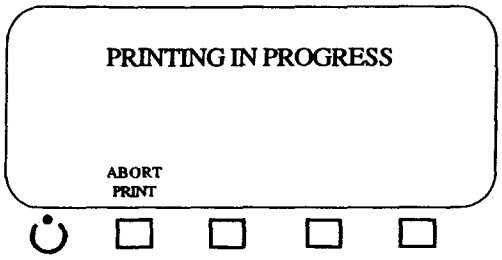
Displaying Scan Results

The Scan Results screen displays B-mode images of the longitudinal and horizontal planes from the largest image found. Each B-mode image displays the area of the bladder cross-section of the respective plane and an icon of a man bisected by the scan plane displayed. This screen can be used to evaluate the results of a scan before printing.



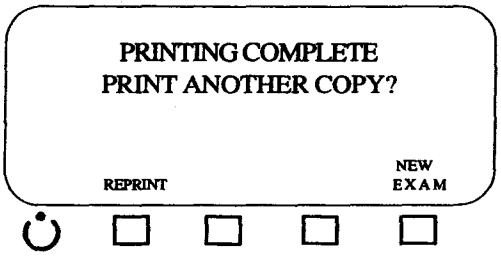
Printing Exam Data

- If no printed output is needed, pressing the SCAN button will return to the Gender screen and the instrument will be ready for another scan. If a printed output is required, press the PRINT button. A "Printing in Progress" message will be displayed and the ABORT PRINT button will allow the user to stop a print in progress. (Printing takes about one minute.)

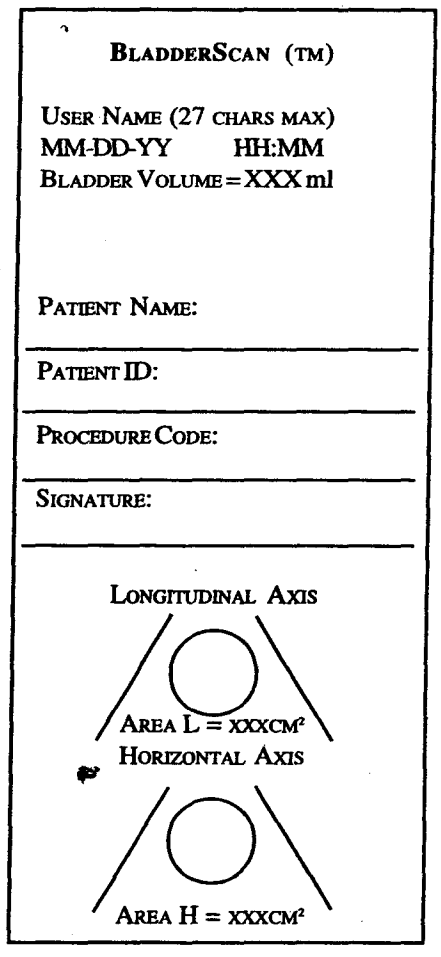


Note: If name, date and time have not been set, those lines will be skipped in the printout. The printout is on thermal paper. Over time, it will fade. For maximum storage life, photocopy the printout.

After the printing is completed or when it is halted, the display changes to the following:



- Pressing the REPRINT button will make a second copy of the scan results. Pressing the NEW button will set the instrument up for a new scan.



Quick Start
For Experienced Users

1. Make sure that the scanhead is plugged in and the battery charger is *not* plugged in.

2. Press the button to turn the BladderScan on.

3. Press the MALE or FEMALE button to indicate the sex of the patient.

4. Put ultrasound gel on the scanhead, being careful to remove air bubbles.

5. Place the scanhead about 3 cm superior to the symphysis pubis pointing toward the expected bladder location. Make sure the head of the icon on the scanhead is pointed toward the patient's head.

6. Press the scanhead button marked . Hold the scanhead steady until you hear a beep. The BVI 2500 will display the volume measured and an aiming display with crosshairs.

7. If the bladder is not centered on the crosshairs, adjust scanhead and repeat the scan until the bladder is properly centered. The BVI 2500 will save the largest bladder volume from any series of scans.

8. When you are satisfied that the result is accurate, press the DONE button. The BVI 2500 will display the largest volume measured and the longitudinal and horizontal B-mode scans.

9. For a printed copy of the results, press the PRINT button.

Additional Features

On-Screen Help

Pressing the HELP button provides on-screen instructions describing how to use the BVI 2500. The Help screen is accessible from most screens and provides information that is displayed six lines at a time. Users can scroll up and down using buttons. They can exit the Help screen by pressing the RET (for return) button; or, if no button has been pressed, after 30 seconds the machine will automatically return to the screen from which help was requested.

Paper Feed

To feed paper through the printer when loading paper or clearing a paper jam, press the ALT button to select the Alternate screen, then press the PAPER FEED button. The screen will display "PAPER FEED" and the paper feed motor will run for 30 seconds or until the FEED STOP button is pressed. When paper feeding stops, the instrument returns to the Alternate screen.

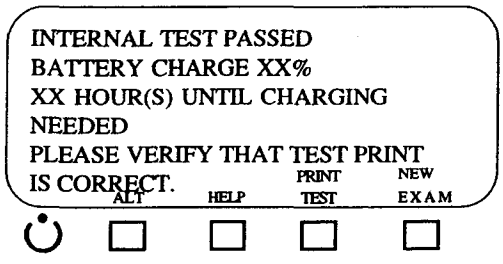
Self-Test

To have the BVI 2500 test itself, from the Alternate screen press the SELF TEST button. The instrument performs the following tests:

Internal Test—Memory and computer circuitry are checked.

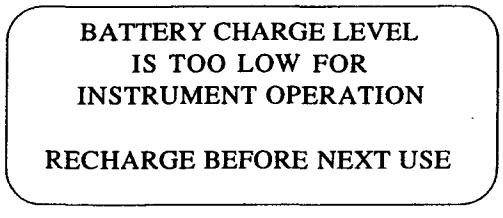
Battery Test—The charge level of the battery is reported as a percentage of full charge and the remaining operating time is estimated.

Printer Test—A character set is printed. The user must verify correct operation. At the end of the tests the following screen will be displayed and users can press NEW EXAM to ready the instrument for scanning.



Recharge Message

Whenever the battery charge level is too low to permit normal operation but not too low to prevent operation of core circuitry (microprocessor, memory, and display), the instrument will display the following recharge message for 30 seconds and then shut down.



Proper Care and Maintenance

Cleaning and Disinfection

The BVI 2500 may be cleaned with a soft cloth dampened in isopropyl alcohol or any standard hospital cleaning solution that does not contain aromatic hydrocarbons.

The round, black, plastic dome of the scanhead that contacts the patient may be disinfected with any disinfecting agent suitable for use with LEXAN polycarbonate. In the United States, Cidex and Cidex 7 are FDA-cleared for this purpose. Follow the instructions provided by the manufacturer of the disinfecting agent. Do not immerse the scanhead beyond the point at which the black plastic dome connects to the black metal body. Do not use Cidex Plus, as it is not recommended for use with LEXAN polycarbonate.

Do not subject any part of the BVI 2500 to steam sterilization or ethylene oxide sterilization.

Calibration

No routine calibration or alignment operations are required.

Inspection

The manufacturer recommends that users perform the following checks approximately once per week. This will ensure that the instrument operates properly and safely at all times.

- √ Inspect the scanhead for cracks that could allow the ingress of conductive fluid and inspect the cable and connector for any apparent physical fault. Do not use the BVI 2500 if any such problem is suspected. No other routine maintenance is required.
- √ Perform the instrument self-test from the Alternate menu and verify that all tests are passed.
- √ Turn the BVI 2500 on while the battery charger is connected and verify that the BVI 2500 correctly detects the battery charger by displaying a screen with: "DISCONNECT BATTERY CHARGER BEFORE PERFORMING EXAM."
- √ Compare pre-void and post-void measurements with the voided volume measured in an accurate beaker. Results should be consistent with the statement of accuracy in "Technical Description."

Caution: In the event of changes in the performance of the instrument, discontinue use and contact the manufacturer.

Battery Disposal

The BVI 2500 contains a sealed lead-acid battery. The battery is not user replaceable and requires no routine maintenance. Safe removal for the purpose of disposal requires that the case bottom and front panel be removed to allow access to the battery mounting screws. It is best to return the instrument to Diagnostic Ultrasound Customer Service for this procedure. The battery manufacturer suggests the following waste disposal method:

Place in an acid resistant container. Dispose of in accordance with federal, state and local regulations. Do not incinerate. Batteries should be shipped to a reclamation facility for recovery of the metal and plastic components as the proper method of waste management.

Fixing Problems

Powerup Self-Test

The BVI 2500 performs a quick test of its computer and memory modules immediately upon powerup. If any errors are detected, the message: "MEMORY SYSTEM ERROR, CONTACT DIAGNOSTIC ULTRASOUND, 800-331-2313, 206-867-1348" will be displayed for five seconds (if possible), then the instrument will turn itself off.

The BVI 2500 also determines if the correct scanhead is connected. If the correct scanhead is installed, the instrument will proceed to the normal powerup state. If no scanhead or an incorrect scanhead is installed, the BVI 2500 will display: "NO PROBE."

Charger Detection

When the BVI 2500 is turned on with the charger still connected the screen will display: "DISCONNECT BATTERY CHARGER BEFORE PERFORMING EXAM." This prevents the instrument from being used with patients while connected to AC power.

BATT Message

A "BATT" message will appear in the lower-right corner of the screen when less than one hour of battery power remains. When it appears, you should begin recharging the battery as soon as possible.

Recharge Message

When the battery charge is too low to allow normal operation but not too low to permit operation of the internal circuitry, a Recharge screen will be displayed reading: "BATTERY CHARGE LEVEL IS TOO LOW FOR INSTRUMENT OPERATION. RECHARGE BEFORE NEXT USE." In such cases the instrument must be recharged.

Clearing Paper Jam

If the paper tape will not feed, pull the latch on the printer cover door toward the front of the instrument to access the paper well. Locate the red lever at the back of the paper well and pull the lever open. Pull the printer cover slightly up and towards the rear of the machine to remove it. Remove the paper roll from the paper well. Then either pull the paper from the paper entry slot to clear or use tweezers to remove the jammed paper from underneath the white printer head that is located behind the printer motor.

Caution: If the paper jam is inaccessible do not try to disassemble the printer. Return the instrument to the manufacturer for service.

Fuse Replacement

If the BVI 2500 fails to operate when the power button is pressed, the user should check the fuse, which is accessible from the rear panel. Replace only with a 5 x 20 mm, T 4 A, 250 V slow-blow (IEC 127/ Sheet III) fuse, Diagnostic Ultrasound part #265-0006.

Warranty

Warranty

Diagnostic Ultrasound Corporation warrants the BVI 2500 against defects in material and workmanship. This warranty applies for 1 (one) year from the date of purchase from Diagnostic Ultrasound Corporation. This warranty is given only to the original purchaser of the BVI 2500.

Pursuant to this warranty, Diagnostic Ultrasound Corporation will repair or replace products which prove to be defective during the warranty period, provided that the repair is performed by Diagnostic Ultrasound or a Diagnostic Ultrasound authorized service organization, and the instrument is returned to Diagnostic Ultrasound Corporation for service.

In some countries, this warranty statement is for information only. Specific warranty terms may be found in the sales contract.

Disclaimer of Additional Warranties

There are no understandings, agreements, representations of warranties, expressed or implied (including warranties of merchantability or fitness for a particular purpose) other than those set forth in the preceding section, "Warranty." The contents of this *Operator's Manual* do not constitute a warranty.

Some states disallow certain limitations on applied warranties. The purchaser, user, and patient should consult state law if there is a question regarding this disclaimer.

The information, descriptions, recommendations, and safety notations in this *Operator's Manual* are based upon Diagnostic Ultrasound Corporation's experience and judgment, as of November 1995, with respect to the BVI 2500. This is a new product involving a relatively new area of medical technology. The contents of this *Operator's Manual* should not be considered to be all inclusive or covering all contingencies.

The physician(s) at your institution directing the use of the BVI 2500 is responsible for keeping current with developments in the literature on bladder volume. Please direct any questions or problems concerning bladder volume, the use of the instrument, or interpretation of data, to the responsible physician(s).

If we may be of assistance to you or your staff please contact us.

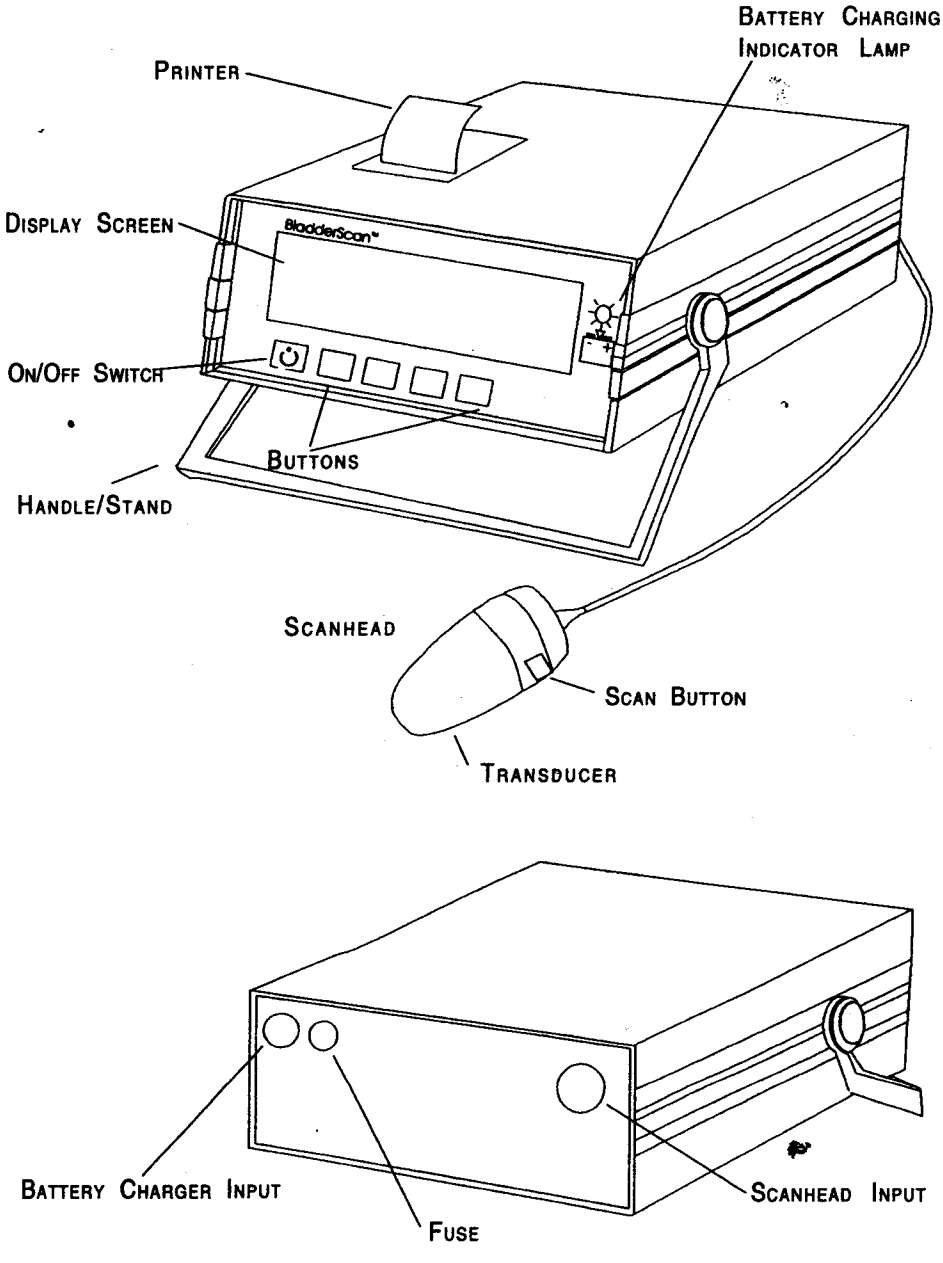
Customer Service Department
Diagnostic Ultrasound Corporation
18109 NE 76th Street
Redmond, WA 98052 USA
US Voice 1 800 331-2313
International Voice 1 206 867-1348
International Fax 1 206 883-2896

Safety and Performance Summary

- The charger interlock prevents the BVI 2500 from operating while the battery is being charged.
- The BVI 2500 computes the volume of the bladder based upon twelve cross sectional images of the bladder. Be sure to hold the scanhead motionless during scans.
- The most accurate measurements are obtained when the patient is resting quietly in the supine position.
- The accuracy of the result is compromised if the user does not obtain an optimal, repeatable image.
- Errors in usage tend to result in underestimation of bladder volume except in cases where the scanhead is moved while scanning is taking place.
- The BVI 2500 is not intended for use on pregnant patients.
- The patient should not have a catheter in the bladder. This could affect the accuracy of the instrument by creating micro bubbles in the bladder.
- Do not use the BVI 2500 on patients with open skin or wounds in the suprapubic region.
- Use care with suprapubic and pelvic surgical patients. Scar tissue, surgical incisions, sutures or staples can affect ultrasound transmission and reflection.
- To save power, the BVI 2500 will turn itself off when not in use.
- Diagnostic Ultrasound recommends that the new user first use the BVI 2500 on a patient with a moderately full bladder, rather than initially attempting to locate a bladder with a low volume.

- **Warning:** There is a possible explosion hazard if the BVI 2500 is used in the presence of flammable anesthetics.

BVI 2500 Components



Parts and Accessories

Quantity	Part Number	Description
1	570-0076	Control Unit
1	570-0024	Scanhead Assembly
1	400-0013	Battery Charger (120 volts) or
1	400-0008	Battery Charger (230 volts)
1	800-0004	Scanhead Holder
1	800-0005	Acoustic Coupling Gel, 0.25 liter
1	265-0006	Fuse, 5 x 20 mm, T 4 A, 250 V (spare)
3	800-0042	Printer Paper
1	900-0051	Operator's Manual

For Further Information

For further information, consult the following journal articles:

1. Cardenas, D.D., Kelly, E., Krieger, J.N., & Chapman, W.H. (1988). Residual Urine Volumes in Patients with Spinal Cord Injury: Measurement With a Portable Ultrasound Instrument. *Archives of Physical Medicine and Rehabilitation,* 69: 514-16.

2. Chadwick, A.T. (1989). BVI 2000™: A Non-invasive Technique to Assess Bladder Function. *Journal of Neuroscience Nursing,* 21: 256-57.

3. Coombes, Graham M., & Millard, Richard J. (1994) The Accuracy of Portable Ultrasound Scanning in the Measurement of Residual Urine Volume *Journal of Urology,* 152: 2083-85.

4. Ireton, R.C., Krieger, J.N., Cardenas D.D., Williams-Burden, B., Kelly, E., Souci, T. & Chapman, W.H. (1990). Bladder Volume Determination Using a Dedicated, Portable Ultrasound Scanner. *Journal of Urology,* 143: 909-11.

5. Massagli, T.L., Cardenas, D.D., & Kelly, E.W. (1989). Experience With Portable Ultrasound Equipment and Measurement of Urine Volumes: Inter-User Reliability and Factors of Patient Position. *Journal of Urology,* 142: 969-71.

6. Meares, E.M. (1991). Current Patterns in Nosocomial Urinary Tract Infections. *Supplement to Urology,* 37: 9-12.

7. Murray, M., (1990). Pediatric Application of the Bladder Volume Instrument. *Journal of Pediatric Nursing,* 5: 290-91.

Technical Description

Compliance with Standards

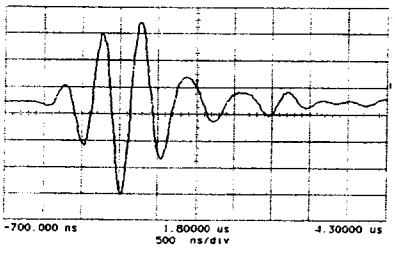
DxU certifies that the **BladderScan** BVI 2500 is in compliance with all applicable international and national standards and regulations, including, but not limited to, IEC-601-1 (EN60601-1) and EN 60601-1-2; MDD 93/42/EEC Annex 1, CSA22.2 No. 125 (Risk class 2) (LR 76129-1), and UL544. Per the provisions of IEC-601-1, this device is classified as:

Protection Class II, INTERNALLY POWERED EQUIPMENT

TYPE BF, suitable for CONTINUOUS USE

Per the MDD, the BVI 2500 is a Class IIa device.

Scanning Specifications



The ultrasound output parameters of the BVI 2500 are as follows:

Temporal Average Power:	1 mW maximum
Focal 20 dB Beam-Area:	1.4 cm^2
Transducer Dimension:	13 mm diameter
Working Frequency:	2 MHz
Peak Instantaneous Intensity:	14 W/cm^2 maximum
Pulse Repetition Frequency:	180 pulses/second

Technical performance assessment (for example, in an acoustic laboratory) may require partial immersion of the scanhead. Immerse the black plastic dome no further than the point at which it connects to the black metal body.

Scanning Accuracy

Given the tremendous variation of healthy and compromised human anatomy, a guaranteed accuracy specification for the instrument used on humans would be difficult. For this reason, the following accuracy specification assumes usage per instructions, scanning a DxU Tissue Equivalent Phantom:

Bladder Volume Range:	0 to 999 ml
Accuracy:	0 to 699 ml ± 20%, ± 20 ml
	700 to 999 ml ± 25%, ± 25 ml

Note: The accuracy that an individual achieves using the BVI 2500 will depend on properly aiming the sensor so that the bladder falls entirely within the measurement cone.

Environmental Conditions for Storage

Ambient temperature from -40 to +70 degrees Celsius

Relative humidity of 10% to 100%, non-condensing

Atmospheric pressure from 50 kPa to 120 kPa

Environmental Conditions for Use

Ambient temperature from +5 to +40 degrees Celsius

Relative humidity of 10% to 90%, non-condensing

Atmospheric pressure from 50 kPa to 120 kPa

Year of Manufacture

The year of manufacture of the instrument is indicated by the first two digits of the serial number shown on the rear panel.

Battery Charger

In North America and Japan, the battery charger input is 120 V~, 60 Hz, 0.1 A and the charger is UL and CSA recognized. Outside North America and Japan, the battery charger input is 230 V~, 50 Hz, 0.1 A and the charger complies with IEC 950 (EN60950) and EMC Directive 89/336/EEC. The battery charger output is 7.3 V ⎓ at 500 mA. Use only the battery charger supplied. The use of any other charger may damage the instrument.

Fuse

Fuse: 5 x 20 mm, T 4 A, 250 V, Slow-blow (IEC 127/Sheet III), D.U. Part #265-0006.

Clock

The internal clock is accurate to better than one minute per month at 25 degrees Celsius. It will operate for at least 10 years from an internal lithium battery. It knows the number of days in each month and will correctly handle February in a leap year.

Avoiding or Identifying and Resolving Adverse Electromagnetic Effects

There are no restrictions for the use of the BladderScan BVI 2500 due to its electromagnetic characteristics. Both the emissions from the BVI 2500, and the susceptibility of the BVI 2500 to interference from other sources, are within prescribed limits of all applicable standards at the date of manufacture. The emissions test procedure used is that specified in EN55011: 1991 for Group 1, Class A equipment (per EN60601-1-2, 36.201.1.7). The BVI 2500 is suitable for use in ISM (industrial, scientific and medical) environments, and in domestic environments under the jurisdiction of a health care professional. An indication of adverse electromagnetic effects from the BVI 2500 on another electronic device would be a degradation of performance in that other device when the BVI 2500 is operated simultaneously. If such interference is suspected, separate the two devices as much as possible, or discontinue simultaneous operation, if practical, and contact Diagnostic Ultrasound.

The BVI 2500 will operate normally in the proximity of other potential interference sources, and has demonstrated immunity at a field strength of 3 V/m (per EN60601-1-2, 36.202.2.1). In addition, the BVI 2500 detects outside interference and will display "RESCAN" instead of a volume measurement if detected interference is of sufficient magnitude to possibly compromise measurement accuracy. If this "RESCAN" display occurs repeatedly, attempt to locate and disable or remove the interference source, or use the BVI 2500 away from the interference source. If these efforts do not restore normal operation, contact the distributor.

No other precautions need be taken as regards exposure in reasonably foreseeable environmental conditions to magnetic fields, pressure or variations in pressure, acceleration, or thermal ignition sources.

Technical Documentation

Diagnostic Ultrasound, upon written request, will make available circuit diagrams and other technical documentation which will assist the user's appropriately qualified technical personnel to repair this equipment. This information is deemed confidential and proprietary and its use is limited solely to such repair applications. Repair should be performed only by Diagnostic Ultrasound or a Diagnostic Ultrasound authorized service organization.

CE Declaration of Conformity
Per EN 45015: 1989

We:

Diagnostic Ultrasound Corporation
18109 N.E. 76th Street
Redmond, WA 98052
United States of America

declare under our sole responsibility that the product:

BladderScan BVI 2500 Bladder Volume Instrument

to which this declaration relates is in conformity with the following standard(s) or other normative documents:

EN55011: 1991/CISPR11, Group 1, Class A, under EN60601-1-2: 1993

EN50082-1: 1992, under EN60601-1-2: 1993

- **IEC801-2: 1991, 3 kV contact discharge and 8 kV air discharge**
- **IEC801-3 (second edition under consideration), 3 V/m**
- **IEC801-4: 1988, 1 kV**
- **IEC801-5 (under consideration), 1 kV differential mode, 2 kV common mode**

Following the provisions of **Directive 89/336/EEC**.

Gerald McMorrow, President

Redmond, WA, U.S.A., September 25, 1995

BVI 2500+ User's Manual Addendum

Measurement Averaging Mode

A measurement averaging option has been added for use, particularly on small bladder volumes typical of post-void residual measurements. This averaging mode must be selected by the user during each examination. Otherwise, the unit operates in the standard non-averaging mode -- where the largest volume measured is retained.

The third function switch from the left on the aiming screen is now labeled "~~AVG~~", with a line drawn through the letters. This indicates that the averaging mode is not operating. To select the averaging mode, momentarily depress the "~~AVG~~" button. The strikethrough will disappear, and the switch label will read "AVG". In addition, the display will reset, and data from any scans previously performed will be cleared.

While in averaging mode, the large numerals display a running average of all volume measurements obtained since entry into this mode. The subscript "AVG" appears adjacent to this display as a reminder that this is a computed average value. The result of the most recent scan is displayed adjacent to the "CURRENT" designator, and the target display is updated with each scan as well.

If "AVG" is pressed while in averaging mode, the instrument toggles back to standard operation, and all data acquired while in averaging mode are cleared. The display will reset, and the strikethrough will reappear in the "~~AVG~~" switch label.

If "DONE" is selected while in averaging mode, the results screen appears, and the large numerals have a subscript "AVG" as a reminder that the value is an average. The cross-sectional images and values are from the most recent scan. This is in contrast to the non-averaging mode, where the images and areas from the scan with the largest volume, which is not necessarily the most recent scan, are displayed.

If "PRINT" is selected from the results screen when averaging mode was active, the printout will contain the average bladder volume, followed by the statement "Average of XX measurements," where XX is the number of scans performed during the averaging mode. (If less than two scans were performed, this statement is omitted, because it would not be meaningful.) Also, the cross-sectional images will be preceded by the statement "Last measurement," as a reminder that the image outlines and area values are those of the last, and not necessarily the largest, scan.

The following procedure will help improve results when using the averaging mode:

First, begin scanning in normal mode, and scan several times to locate the bladder and center the probe. Remember to adjust the aim of the probe only between scans, and to hold the probe steady while scanning. Scan repeatedly and adjust aim until the bladder image is well-centered on the target.

Next, press the "~~AVG~~" switch on the control box to begin averaging mode. Resume scanning, keeping the probe centered on the bladder. Observe the target display to verify that the aim remains consistent.

Repeat scanning as desired. The instrument will continue to update the average value as long as you keep scanning. When sufficient scans have been performed, press the "DONE" switch on the control box to save the average measurement value.

Histogram Display and Printout

The BVI 2500+ will remember how many bladder measurement exams have been performed and will classify them according to the volume range of the results. This utility is accessible from the self-test menu screen, which is a sublevel of the alternate menu. A histogram classifying these measurements can be viewed and printed by pressing the right-most function switch, labeled "HIST". Beginning a new exam from the self-test screen may still be accomplished by selecting "ALT" to return to the alternate menu, and then selecting "RET" from there to return to the main menu screen.

When "HIST" is selected, the screen displays six volume ranges and the number of exams whose measurements are within each range. For the purposes of this histogram, an exam is counted when its printout is initiated. If the configured language is English, the display will also show estimates of the numbers of catheterizations and urinary tract infections which have been avoided by use of the BVI 2500+, and an estimate of the total dollar savings resulting from its use. It should be understood that these are estimates only, based upon available data on the bladder volume range in which catheterization is typically forgone; the average incidence and severity of nosocomial urinary tract infections and the percentage of those estimated to be due to catheterization; the average cost of a urinary catheter; and the average daily cost of a hospital stay.[1] The results obtained by a given user will likely be different than these estimates.

The histogram information may be printed by selecting "PRINT" from the histogram screen. The printout provides the information in slightly greater detail, using eleven volume ranges. After a printout is obtained, the user may elect to clear the stored count data by pressing "RESET." The displayed values will all reset to zero, and counting will begin anew with the next exam. Note that the data may not be reset until after a printout is generated. Finally, the user may return to the self-test screen by selecting "RET."

[1]Data on the incidence of catheter-induced nosocomial urinary tract infection and its associated costs are from:
Cox, Claire E. (1988). Nosocomial Urinary Tract Infections. *Urology, 32(3):* 210-215.

FOR SERVICE CONTACT:

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